K060809

# 510(K) SUMMARY

JUL - 3 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. **Submitter's Name:** **PROMED Advance Technology Co., Ltd.**
   **Address:** 2F-5, No. 289, Sec. 1, Dunhua S. Rd., Taipei 10689 , TAIWAN
   **Phone:** +886-2-27007859
   **Fax:** +886-2-27084599
   **Contact:** Mr. Wilson Yeh / Vice President

2. **Device Name :**
   **Trade Name:** **Osteo-Link Bone Void Filler Pellets**
   **Common Name:** Calcium sulfate
   **Classification name** filler, bone void, calcium compound

3. **DEVICE CLASS** **Osteo-Link Bone Void Filler Pellets** have been classified as
   Regulatory Class: II
   Product Code: MQV
   Panel : Orthopedic
   Regulation Number: 21CFR 888.3045

4. **Predicate Device:** The predicate device is the
   - **Wright Plaster of paris pellets(K963562)** marketed by **WRIGHT MEDICAL TECHNOLOGY, INC.**

5. **Device Description:** **Osteo-Link Bone Void Filler Pellets** are made of high purity pharmaceutical grade calcium sulfate. The biodegradable, radiopaque pellets are resorbed in approximately **14 weeks** when used according to labeling. **Osteo-Link Bone Void Filler Pellets** are provide sterile for single patient use.

**6. Intended Use:** **Osteo-Link Bone Void Filler Pellets** are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. These pellets are indicated to be gently packed into bony voids or gap of the skeletal system; such as the extremities, spine and pelvis. Theses defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets provide the bone void filler that resorbs and is replaced with bone during the healing process.

**7. Performance Summary:** The device conforms to applicable standards includes ISO 10993 series : Biological evaluation of medical devices , ASTM F2224-03□Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants & ANSVAAMI/ISO 11137 Sterilization of Health Care Products - Radiation Sterilization.

8. Conclusions:

The **Osteo-Link Bone Void Filler Pellets** has the same intended use and similar technological characteristics as the **Wright Plaster of paris pellets(K963562)** marketed by **WRIGHT MEDICAL TECHNOLOGY, INC.**.

Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Osteo-Link Bone Void Filler Pellets** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

PROMED Advance Technology Co., Ltd.
% Harvest Consulting Corporation
Ms. Jennifer Reich
2904 N. Boldt Drive
Flagstaff, Arizona 86001

Re: K060809
Trade/Device Name: Osteo-Link Bone Void Filler Pellets
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulation Class: II
Product Code: MQV
Dated: June 16, 2006
Received: June 19, 2006

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Rucker

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K060809

Device Name: **Osteo-Link Bone Void Filler Pellets**
**PROMED Advance Technology Co., Ltd.**

Indications For Use:

Osteo-Link Bone Void Filler Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. These pellets are indicated to be gently packed into bony voids or gap of the skeletal system; such as the extremities, spine and pelvis. These$ defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets provide the bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ducharme

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K060809